Legal Aspects of Clinical Drug Research

Abstract

The aim of this work is the evaluation of the current situation in the clinical study of medication, description of the rights and the protection of the subject of evaluation in the research and solution of selected questions, which may be confusing or at least unclear for the average person. Furthermore, this thesis discusses the exercise of the rights of the subject of the research with focus on damages incurred by the subject of evaluation and to his close persons. The last question is payment for participation in clinical research and other benefits that the subject of the evaluation gains for the participation.

Through this methodology, this work has resulted in a detailed analysis of the rights of the subject, especially in relation to his / hers personal rights, their protection and performance. Through the method described above, it brings a new perspective on the relationship of liability for the damage caused to the subject of the clinical research. It also presents arguments pointing to the necessity to change the actual but legally unsatisfactory status of the reimbursements provided for participation in the clinical research.

The main findings of this work are the clarification of the liability in relationships that arise in clinical research. They are essentially the objective liability of the contract owner and, in most cases, the subjective responsibility of the healthcare provider and the description of the practically provided remittances; the questions why the research needs to be provided and why the current legislation is inadequate are answered.

The thesis is solved within the current legal regulation in the context of European and international law with a short historical perspective on the development of the legal regulation of clinical research.

Keywords: clinical study, protection, subject,